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The value of randomisation

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Randomisation is an often used term in statistics and research. For example, many statistics textbooks state that the data for an Analysis of Variance (ANOVA) must come be a random sample from the population [1]. Many researchers, however, do not appreciate the meaning of randomisation or the benefits it can bring to human experimentation. In common usage, random refers to something odd or unusual [2]. The Oxford English Dictionary defines the term random as *"Made, done, or happening without method or conscious decision."*[2] While Everitt[3] defined random as *"Governed by chance; not completely determined by other factors. Non-deterministic."* When used in statistics and experimental design, researchers should understand that randomisation is not a haphazard process[4, 5] and the term "non-deterministic"[3] is a key phrase.

Randomisation a process can be traced back to the 1920s [6], although there are reports of Charles Peirce and Karl Pearson advocating its use in the 19th century [7]. However, the modern use of randomisation is driven by the work of RA Fisher and AB Hill [6, 8]. Fisher from a statistical theory standpoint, noting that randomisation was a way to ensure samples were drawn independently[6, 9]. Hill, approached it from a more practical need [6, 10] governed by a desire to remove bias from scientific results.

Studies examining the effect of a given treatment require two groups for comparison.[11, 12] It is a common research strategy, which begins with either the wish or the assumption that the two groups are alike in all independent variables that can influence the outcome variable.[12] If this is true, any differences in the outcome variable can be attributed to the effect of the treatment under investigation,[11, 13] and statistical techniques can measure the likely effects of chance.[13] However, if the groups are selected either by the researcher or self-selected, this is unlikely. Study groups like

these are involved in observational studies and the two groups may differ in several important ways. Randomisation is a process that can ensure the balanced distribution of factors between groups.[14]

Randomness refers to how a sample is obtained.[10] The aim of randomisation is to ensure a fair comparison between like groups.[14] This is achieved by eliminating biases that can lead to systematic differences between groups.[4] Randomisation generates groups that are similar, but not identical.[15] In allocating participants to groups, the participants individual characteristics are not considered in the process.[13] Consequently, randomisation gives advantages to the researcher that would be otherwise unobtainable. The researcher's idiosyncrasies,[4, 16] personal judgement,[4, 16] and potential biases [4] are removed from the equation.

Clinicians are trained to use their judgement to make choices on behalf of their patients.[17] For that reason randomisation might not appeal as the best option. But, personal judgement also introduces biases. The unpredictability of the process gives a defence against allocation bias, especially if participants are not blinded to their treatment allocation.[18] Randomisation is not a haphazard process it is one that needs careful planning. Several variants exist; simple, blocked and stratified, and which is used is determined by the experimental design.[7] It can be conducted with a random number table or flipping a coin,[5] but to ensure its integrity it is best carried out using a computer program (See appendix 1).[10, 13, 19]

Randomisation is a valuable tool available to researchers. Besides being integral in a randomised controlled trial, it is used in a cross over trial where each participant receives each treatment on different occasions.[7] Despite its name, it should be a planned process that requires a lot of thought on the part of the investigator. It adds strength to a study, and rather than be avoided randomisation should be regarded as a principle of research.[12, 16] Kerlinger[12] advised that if researchers want to control the effects of independent variables they should, randomly select participants and randomly assign participants to groups, then the experimental treatments should be randomly assigned to those groups.

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Appendix 1

R code for a simple random sample

Random assignment for a sample of 30

```
FlipCoin = function(n) sample(0:1,n,rep=T)
e1=FlipCoin(30)
table (e1)
e1
write.csv(e1, file = "sample30CSV.csv")
```